



If Novartis fails to prove any of these four elements, then its advice of counsel defense fails.

Because Novartis has the burden to prove these elements, Plaintiffs have no burden to prove that Novartis did not act with a good faith belief with respect to their conduct. But Plaintiffs presented certain evidence at trial that they argue calls into question whether Novartis sought legal advice in good faith, whether Novartis fully laid out all the relevant facts to its lawyers, whether Novartis's lawyers provided advice that its conduct was legal, and whether Novartis followed its lawyers' advice honestly and in good faith. In determining whether or not Novartis has met its burden on the advice of counsel defense, you must consider all of the evidence received in the case.

Sources: *United States v. Colasuonno*, 697 F.3d 164, 181 (2d Cir. 2012) (quoting *Williamson v. United States*, 207 U.S. 425, 453 (1908)); *see also Markowski v. SEC*, 34 F.3d 99, 104-05 (2d Cir. 1994) (defendant may not rely upon advice of counsel defense if defendant either: (i) failed to make complete disclosure to counsel; (ii) did not receive advice that its conduct was legal; or (iii) did not rely on that advice in good faith); *United States v. Evangelista*, 122 F.3d 112, 117 (2d Cir. 1997); *United States v. King*, 560 F.2d 122, 132 (2d Cir. 1977) (a "businessman who knows that" important "factual representations are untrue" cannot "screen himself by trying to rely on advice of counsel"); *United States v. Seminerio*, 680 F. Supp. 2d 523, 542 (S.D.N.Y. 2010).

## **2. Number of False Claims**

If you find that Novartis did violate the False Claims Act, then you need to identify the number of false claims it caused to be submitted to a federal healthcare program.

Each separate demand for payment of government money that you determine is false or fraudulent constitutes a separate claim. It is your duty to tally the number of false or fraudulent claims for which you find that Novartis is liable. Here, the number of false claims is equivalent to the number of separate false claims for fills or refills of Exjade or Myfortic that the specialty pharmacies submitted for pharmaceutical prescriptions paid by federal healthcare programs seeking payment. You should include claims in your total count regardless of whether or not they were actually paid by a government health plan. Liability attaches once a claim has been submitted to a government health plan for payment.

Novartis did not submitted claims itself, so the issue is whether Novartis caused false claims to be submitted by specialty pharmacies. When a defendant is removed from the claims submission process, as Novartis was in this case, a defendant causes a false claim to be submitted if its fraudulent conduct was a substantial factor in causing the claim to be filed and it was reasonably foreseeable that defendant's actions would result in false claims. In determining whether Novartis's conduct caused false claims to be submitted, you must, therefore, determine that whether Novartis's conduct was a substantial factor in producing the harm and that the outcome was foreseeable.

In order for Novartis to cause a false claim to be made, it is not necessary for Novartis to actually receive any government funds. Therefore, in evaluating causation in this case, it is the knowledge and conduct of Novartis that matters. Therefore if you find that Novartis knowingly caused another to submit a false or fraudulent claim, then you must find that Novartis caused that claim to be filed.

There will be a space in the verdict form for you to place this number should you find that Novartis violated the False Claims Act.

Sources: 31 U.S.C. § 3729(a); *see also United States v. Ehrlich*, 643 F.2d 634, 638 (9th Cir. 1981) (where FCA defendant has knowledge of the number of false claims that defendant causes another to submit, then “he is liable of an equal number [ ]”); *United States v. Village of Island Park*, 888 F. Supp. 419, 441 (E.D.N.Y. 1995).

### 3. False Claims Act Damages

The Plaintiffs are not required to prove that the United States was actually harmed by the false or fraudulent claims.

The measure of the government's damages under the False Claims Act is the amount of money that the government paid out by reason of the false claims. Here, if you find that Novartis is liable under the False Claims Act, the amount of damages is the amount of money that federal healthcare programs paid for false claims that Novartis caused to be submitted.<sup>1</sup> This is so because the federal healthcare programs are, essentially, insurance plans with conditions. Contractors who seek to be paid for products or services by a federal healthcare program must certify that they will abide by those conditions. Therefore, when one of those material conditions of payment is not met, nothing is due.<sup>2</sup>

---

<sup>1</sup> *United States ex rel. Freedman v. Suarez-Hojos*, 2012 4344199, at \*4 (M.D. Fla. Sept. 21, 2012) (collecting cases); *see also U.S. ex rel. Longhi v. Lithium Power Tech., Inc.*, 575 F.3d 458, 472-473 (5th Cir. 2009) (stating that the amount of the government's damages relating to research grants it provided was the total amount of the grants); *United States v. TDC Mgmt. Corp., Inc.*, 288 F.3d 421, 428 (D.C. Cir. 2002) (affirming district court's decision to determine damages based on what the government would have paid out had it known the truth); *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1011 (5th Cir. 1973) (damages under a prior version of the FCA "must be measured by the amount wrongfully paid to satisfy the false claim"); *U.S. ex rel. Liotine v. CDW Government, Inc.*, 2012 WL 2807040, at \*10-11 (S.D. Ill. July 10, 2012) (holding that damages should be equal to the entire amount that the government paid for products sold by defendant where defendant failed to comply with a federal statute that was a precondition for the defendant's sales to the government).

<sup>2</sup> *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) ("The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When those conditions are not satisfied, nothing is due. Thus, the entire amount that Edgewater received on these 1,812 claims must be paid back"); *see also U.S. ex rel. Compton v. Midwest Specialties*, 142 F.3d 296 (6th Cir. 1998); *U.S. ex rel. Roby v. Boeing*, 302 F.3d 637 (6th Cir. 2002) (measure of damages is full contract price when contractor submits claims which do not meet the contracted specifications).

The value of the pharmaceuticals Novartis provided is not relevant to the determination of the government's damages.<sup>3</sup> This means that you do not need to calculate the value of any discount Novartis gave to any specialty pharmacy. You need only calculate the amount the government paid for false claims that Novartis caused to be submitted.

Sources: *United States v. Neifert-White Co.*, 390 U.S. 228, 232; *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008); *U.S. ex rel. Antidiscrimination Center of Metro New York, Inc. v. Westchester County*, 2009 U.S. WL 1108517, at \*2-3 (S.D.N.Y. Apr. 24, 2009); *see also United States v. Mackby*, 339 F.3d 1013, 1014–15 (9th Cir. 2003).

---

<sup>3</sup> *Rogan*, 517 F.3d at 453; *see also U.S. ex rel. Antidiscrimination Center of Metro New York, Inc. v. Westchester County*, 2009 U.S. WL 1108517, at \*2-3 (S.D.N.Y. Apr. 24, 2009) (precluding defendant from presenting evidence to reduce damages under a “benefit-of-bargain” theory); *United States v. Mackby*, 339 F.3d 1013, 1014–15 (9th Cir. 2003) (upholding damages award based on entire amount of Medicare payments where defendant was ineligible to bill Medicare for services, irrespective of whether services were actually performed); *United States v. Neifert-White*, 390 U.S. 228, 232 (1968); *Roby*, 302 F.3d at 646 (“FCA damages ‘typically are liberally calculated to ensure that they afford the government complete indemnity for the injuries done it.’” (internal citations omitted)).

**4. False Claims Act Damages: Preponderance of the Evidence**

As with the other elements of a False Claims Act violation, the plaintiff must prove damages only by a preponderance of the evidence. In other words, that the amount of damages the Government sustained was more likely than not equal to the amount of damages you find in your verdict.

Source: 31 U.S.C. § 3731(d).

## 5. Precision of Damages

In computing any damages sustained by the Government in this case, you do not have to determine the actual damages with precision. If you find that the defendant has by its own acts prevented a precise computation of damages, you may make a just and reasonable estimate based on the relevant data and render your verdict accordingly. In such circumstances, juries are allowed to act upon probable and inferential proof, as well as direct and positive proof. Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victims and would be an inducement to make wrongdoing so effective and complete in every case so as to preclude any recovery by rendering the measure of damages uncertain. The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.

Sources: *New York v. Hendrickson Bros., Inc.*, 840 F.2d 1065, 1077 (2d Cir. 1988) (plaintiff's burden of proving what would have been paid absent collusion is lightened where "there is a dearth of market information unaffected by the collusive action of the defendants"); *Samaritan Inns v. District of Columbia*, 114 F.3d 1227, 1235 (D.C. Cir. 1997) (noting that "the fact that an estimate is uncertain or inexact will not defeat recovery, once the fact of injury is shown"); *see also Miller v. Holzmann*, 563 F. Supp. 2d 54, 108 (D.D.C. 2008) (stating principle in FCA case), *vacated in part on unrelated grounds*, 608 F.3d 871 (D.C. Cir. 2010).